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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,590	09/27/2001	Yung-Ming Chen	50623.00120	4003

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT PAPER NUMBER

1734

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/966,590

Applicant(s)

CHEN ET AL.

Examiner

Laura E. Edwards

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-8 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10-11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuffle et al (US 6,067,480).

Stuffle teaches an applicator for manufacturing biomedical prosthetics comprising a body portion (41), a nozzle (42) including an orifice extending from the body portion, and a temperature controller (80) coupled to the nozzle in proximity to the orifice to change the temperature of the coating as the substance passes through the orifice, wherein the temperature controller is sized to change the temperature of the coating at a concentrated area of the nozzle to prevent exposure of the coating to the change in temperature along the length of the body portion. Inherently, the Stuffle the applicator is capable of coating a stent because a stent is a biomedical prosthetic and the temperature is controlled as evidenced by claim 5 (see col. 5, lines 12-15 and 22-24).

With respect to claim 3, see col. 5, lines 29+. Note that Stuffle does not teach a therapeutic substance and is not required to teach such a substance as the claim specifies the substance to be optional.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stuffle et al (US 6,067,480) in view of Leidner et al (US 6,056,993).

Stuffle et al teach an applicator for manufacturing biomedical prosthetics but is silent concerning the polymer compositions used therewith can include therapeutic substance. However, it was known in the art at the time the invention was made, to provide a therapeutic agent in a polymer composition used in the manufacture of stents as evidenced by Leidner et al (see col. 8, lines 64+). It would have been obvious to one of ordinary skill in the art seeking to manufacture a prosthetic such as a stent to include therapeutic agents, as taught by Leidner et al, in the polymer composition applied by the Stuffle applicator.

Claims 1-3, 5-8, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leidner et al (US 6,056,993) in view Stuffle et al (US 6,067,480).

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Leidner et al disclose an apparatus for manufacturing a stent or biomedical prosthetic device using polymeric based compositions comprising a conventional coating applicator (i.e., extruder, sprayer nozzle, etc.; see col. 14, lines 30-47) for providing [hot] melt coating material to a mandrel (12). Leidner et al are silent concerning particulars to the nozzle including the nozzle including a temperature controller coupled thereto in proximity to the nozzle orifice to change the temperature of the coating as the substance passes through the orifice, wherein the temperature controller is sized to change the temperature of the coating at a concentrated area of the nozzle to prevent exposure of the coating to the change in temperature along the length of the body portion. However, it was known in the prosthetic manufacturing art, at the time the invention was made, to provide a temperature controller or heater circumscribing the outlet orifice of the applicator in order to prevent degradation of the polymeric composition as evidenced by Stuffle et al (see col. 5, lines 22-24). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Stuffle et al about the outlet orifice of the Leidner et al coating applicator in order to prevent degradation of the polymeric composition before it is applied to the prosthetic device.

With respect to claim 3, see Leidner et al, col. 8, lines 64+ for polymer compositions used.

With respect to claim 5, Leidner et al recognize the use of extruder or spraying type coating applicators (see col. 10, lines 24-28 and col. 14, lines 42-46) such that placement of a temperature controller as taught by Stuffle et al about the outlet orifice of a given applicator to prevent coating degradation is within the level of ordinary skill in the art.

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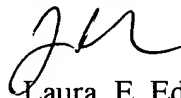
With respect to claim 7, the use of an air-assisted sprayer is deemed to fall within the list of conventional coating applicators as suggested by Leidner et al such that the recitation of internal or external air assisted sprayers does not result in patentability.

With respect to claim 8, the use of a temperature modulator is deemed to be within the level of ordinary skill in the art in order to maintain consistency in the polymeric product applied to the prosthetic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura E. Edwards whose telephone number is (703) 308-4252. The examiner can normally be reached on M-Th/First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (703) 308-3853. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Laura E. Edwards  
Primary Examiner  
Art Unit 1734

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September 30, 2003